

CLAIM LISTING

1. A method for implanting a hearing aid in a patient so as to extend percutaneously into the patient's outer ear canal, said method comprising:
- 5 providing an elongate shaft having an outer wall surrounding at least one elongate lumen extending through said shaft to a distal end;
- tunnelling said shaft from a location behind the patient's pinna to position said shaft distal end in subcutaneous tissue proximate to said patient's ear canal;
- 10 inserting an elongate tool through said lumen so as to position a tool cutting edge proximate to shaft distal end;
- advancing said tool cutting edge past said shaft distal end to form a percutaneous hole opening into said ear canal;
- providing a hearing aid housing having a stud projecting
- 15 therefrom; and
- transporting said housing through said lumen to said shaft distal end to position said stud in said percutaneous hole opening into said ear canal.
- 20 2. The method of claim 1 wherein a porous layer is provided on the peripheral surface of at least a portion of said housing for promoting tissue ingrowth.
3. The method of claim 1 wherein said tunnelling step includes
- 25 providing an obturator to close said lumen proximate to said shaft distal end.
4. The method of claim 1 further including inserting an anvil in said patient's ear canal; and wherein
- said step of advancing said tool cutting edge includes engaging said cutting edge against said anvil.
- 30 5. The method of claim 1 wherein said housing carries at least one anchor configured for movement between a retracted position and a deployed position;

and wherein when said housing is being transported through said lumen said anchor is retracted and when said housing engages said subcutaneous tissue said anchor is deployed to retain said housing adjacent to said percutaneous hole.

5

6. The method of claim 1 wherein said step of providing said elongate shaft includes providing a shaft having a flat bevel edge at its distal end for facilitating the separation of skin from bone while tunneling.

10

7. The method of claim 1 wherein said step of providing an elongate shaft includes providing a shaft outer wall having a noncircular cross-section.

15

8. The method of claim 1 wherein said step of providing an elongate shaft includes providing an elongate lumen having a noncircular cross-section.

20

9. The method of claim 8 wherein said step of providing a hearing aid housing includes providing a housing having a noncircular cross-section corresponding to said lumen cross-section.

25

10. The method of claim 1 further including providing a movable door for normally closing the open distal end of said shaft; and wherein said step of inserting said tool through said lumen to said distal end acts to open said door.

30

11. The method of claim 1 including the further step of inserting a tool into said ear canal for pushing said stud back into a desired position relative to said ear canal.

12. The method of claim 1 wherein said step of providing an elongate shaft includes providing visible depth markings on said shaft for

facilitating the positioning of said shaft distal end proximate to said patient's ear canal.

//

//

5 //

//

//

//

//

10 //

//

//

//

//

15 //

//

//

//

//

20 //

//

//

//

//

25 //

//

//

//

//

30 //

//

//

//

13. A medical device configured for implantation at a subcutaneous site in a patient's body comprising:

5 a housing defining a body portion configured for mounting subcutaneously proximate to a patient's ear canal and a stud portion extending from said body portion for percutaneously projecting into said ear canal;

said body portion defining a noncircular cross-section; and
a porous layer carried by a peripheral surface area of said housing for promoting soft tissue ingrowth.

10

14. The medical device of claim 13 further including an electroacoustic transducer mounted in said housing for projecting sound energy from said stud portion.

15 15. The device of claim 14 further including at least one anchor carried by said housing configured for movement from a retracted position to a deployed position for engaging soft body tissue.

//

//

20 //

//

//

//

//

25 //

//

//

//

//

30 //

//

//

//

16. In combination, a hearing aid housing and an instrument set for transporting said housing through a subcutaneous tunnel from a location behind a patient's pinna to a subcutaneous location proximate to the patient's ear canal, said combination comprising:

5 said instrument set including an elongate shaft having a distal end configured for tunneling through soft body tissue to said subcutaneous location proximate to said ear canal, said shaft defining a lumen extending from an entrance opening to an exit opening at said distal end;

 said hearing aid housing configured for passage through said
10 entrance opening, said lumen, and said exit opening; and

 a pusher member configured for axial movement in said shaft for pushing said housing through said lumen for implanting at said subcutaneous location.

15 17. The combination of claim 16 wherein said lumen has a noncircular cross-section; and wherein

 said housing has a noncircular cross-section corresponding to said lumen cross-section.

20 18. The combination of claim 16 further including means for threadedly engaging said pusher member and said shaft for enabling said pusher member to be rotated to axially advance said housing toward said exit opening.

25 19. The device of claim 16 wherein said housing includes a body portion and a stud portion defining a longitudinally extending peripheral surface, and a shoulder between said body portion and said stud portion defining a laterally extending peripheral surface; and wherein

 a porous layer is formed on said longitudinally and/or laterally
30 extending peripheral surfaces to promote tissue ingrowth.

20. The combination of claim 16 further including:

at least one anchor carried by said housing configured for movement between a retracted position and a deployed position; and wherein

5 said anchor is held in said retracted position when said housing is in said lumen and is configured to automatically move to said deployed position when said housing is ejected from said shaft exit opening to engage subcutaneous tissue.

21. The combination of claim 16 wherein said instrument set
10 further includes:

 a hole forming tool having an elongate shank configured for removable insertion through said shaft lumen for forming a percutaneous hole opening into said patient's ear canal.

15 22. The combination of claim 21 wherein said elongate shank has a cutting edge at its distal end for cutting said percutaneous hole.

 23. The combination of claim 22 wherein said shank is mounted for axial rotation to facilitate said cutting edge forming said percutaneous hole.

20

 24. The combination of claim 22 further including means for selectively advancing said cutting edge beyond said shaft distal end for cutting said percutaneous hole.

25 25. The combination of claim 24 wherein said tool cutting edge defines a periphery for removing a plug of body tissue to form said percutaneous hole; and

 a rod movable relative to said cutting edge for removing any body tissue captured by said cutting edge.

30

 26. The combination of claim 24 wherein said shank is hollow and said cutting edge defines a periphery for capturing a plug of body tissue to form said percutaneous hole; and

a rod axially movable through said shank for ejecting said plug into said patient's ear canal.

27. The combination of claim 24 further including means for
5 threadedly engaging said hole forming tool and said shaft whereby said tool can be axially rotated to incrementally advance said tool shank relative to said shaft.

28. The combination of claim 22 wherein said hole forming tool and shaft are cooperatively configured to permit said tool to be axially
10 rotated in a first mode to incrementally advance said tool shank relative to said shaft and in a second mode for freely spinning said shank in said shaft.

29. The combination of claim 24 further including an anvil surface insertable into a patient's ear canal to allow said tool cutting edge to bear
15 against said anvil surface to form said percutaneous hole.

30. The combination of claim 29 including a speculum having first and second jaws operable to spread said patient's ear canal to increase visibility; and wherein
20 said anvil surface is formed on at least one of said jaws.

31. The combination of claim 16 wherein said shaft bears depth markings on its outer surface for indicating the magnitude of penetration of said shaft distal end.
25

32. The combination of claim 16 wherein said instrument set further includes:

an elongate obturator having a shank configured for removable insertion through said shaft lumen for closing said exit opening.
30

33. The combination of claim 16 further including a movable door mounted on said shaft for normally closing the open distal end of said lumen, said door being configured to be opened by a tool passed through said lumen.

5 //

//

//

//

//

10 //

//

//

//

//

15 //

//

//

//

//

20 //

//

//

//

//

25 //

//

//

//

//

30 //

//

//

//